K071087

1. Device Name

OCT 16 2007

Trade Name: Vis-U-All Heat Seal Pouch and Tubing

Common/usual Name: Sterilization pouch

Classification Name: Sterilization wrap (21 CFR 880.6850 Product Code KCT).

2. Predicate Devices

- Sterrad Sterilization Pouch (K951295)
- Surgicot Pouches, Peel Open, Breathable (K771032)

3. Description of Device

The proposed Vis-U-All Heat Seal Pouch is a Tyvek/plastic film sterilization containment pouch designed for devices to be sterilized by the health care provider by the AMSCO® V-PRO 1 Low Temperature Sterilization System. The purpose of this submission is to demonstrate the Vis-U-All Heat Seal Pouch is qualified for use in the AMSCO® V-PRO 1 Low Temperature Sterilizer. The 510(k) number for the AMSCO® V-PRO 1 Low Temperature Sterilizer is K062297 cleared on October 4, 2007.

4. Intended Use

The Vis-U-All Heat-Seal Pouch and Tubing have been qualified by STERIS Corporation as suitable for use by health care providers to enclose and seal other medical devices to be sterilized in the AMSCO® V-PRO 1 Low Temperature Sterilizer. The system is designed to maintain sterility of properly processed medical devices during normal handling and storage until the pouch is opened and the medical device is removed for use.

5. Description of Safety and Substantial Equivalence

The Vis-U-All Heat Seal Pouch and Tubing object of this Premarket submission are substantially equivalent to the STERRAD Sterilization Pouch (K951295) which is also suitable for use in Vapor Hydroxide Sterilization System. The materials of composition for the Vis-U-All Heat Seal Pouch and Tubing have not changed in their composition from the predicate, K771032. The plastic film (polymylar) thickness has changed to 2.0mil. The device has no chemical indicators.

Performance testing of the Vis-U-All Heat Seal Pouch and Tubing demonstrated that the proposed pouch is qualified for use in the AMSCO® V-PRO 1 Low Temperature Sterilizer and is as safe, as effective, and performs the same as the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 16 2007

Mr. John R. Scoville
Regulatory Affairs
STERIS Corporation
5960 Heisley Road
Mentor, Ohio 44060-1834

Re: K071087
Trade/Device Name: Vis-U-All Heat Seal Pouch and Tubing
Regulation Number: 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: II
Product Code: KCT
Dated: September 12, 2007
Received: September 13, 2007

Dear Mr. Scoville:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K071087

Device Name: **Vis-U-All Heat Seal Pouch and Tubing**

Indications For Use:

The Vis-U-All Heat-Seal Pouch and Tubing have been qualified by STERIS Corporation as suitable for use by health care providers to enclose and seal other medical devices to be sterilized in the AMSCO V-Pro 1 Low Temperature Sterilizer. The system is designed to maintain sterility of properly processed medical devices during normal handling and storage until the pouch is opened and the medical device is removed for use.

Prescription Use _____ AND/OR Over-The-Counter Use __X___
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Shula A Murphy RD
(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices
(Division Sign-Off) Number: K071087